FYI

Joan L. Brown

325 Aragon Ave.
Los Alamos, NM 87544

Home Phone 505 672-1534
Email skjlbrown@aol.com

1280 '99 JUN -8 P1:41

May 28, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Docket # 98N-1265

To Whom It May Concern:

It is my understanding that there are a number of issues in the Memorandum of Understanding on Interstate Distribution of Compounded Drug Products drafted 12/23/98 that are of concern to pharmacies which compound drugs. My primary concerns with this MOU, however, are as a consumer of compounded drugs and as the resident of a state which may elect to sign this memorandum.

As I understand Section III.C.1.a, an "inordinate" amount of compounded drugs dispensed or distributed interstate annually by a pharmacy or physician is defined rather arbitrarily as that amount which is equal to or greater than 20% of the total number of prescriptions dispensed or distributed intrastate and interstate by such pharmacy or physician. In other words, if a given pharmacy wished to specialize in compounding medications, it would be very difficult to do so. That pharmacy would be required to dispense and distribute medications already produced by pharmaceutical companies and would have to dispense and distribute them in amounts at least five (5) times the amount of any compounded drugs dispensed or distributed interstate by them. Section III.C.1.b. further limits the compounding pharmacy or physician: even if the amount of compounded drugs dispensed or distributed complies with the less-than-20%-rule above, it may not dispense or distribute interstate any one or more INDIVIDUAL compounded medications in amounts exceeding 5% of the total number of prescriptions dispensed or distributed by that pharmacy. In other words, if that pharmacy is known to be especially reliable in compounding a particular drug, say an estrogen-replacement drug, and so is used by a large number of physicians, and/or if that pharmacy responds quickly to prescription requests, and/or it prices its product lower than a competitor, it has to be sure to dispense and distribute, both interstate and intrastate, prescription medications amounting to 95% or more of the individual compounded drug. If this interpretation is correct, these regulations would seem to discourage compounding by pharmacies or physicians by failing to reward excellence in compounding, timeliness in responding to prescriptions, and would discourage healthy competition which keeps prices in check. There would also be an incentive to use an already manufactured drug when a compounded medication might be more beneficial for a particular patient. Further, I fail to see how these regulations might provide protection to the U.S. consumer or provide the public with "access to the widest possible range of treatment options consistent with the protection of the public health."

98N-1265

C 3195

Section III.A. and B. sets forth the responsibilities of any state which signs the MOU. At a time when the financial resources of my state in particular are limited, the burden for investigating and responding to complaints relating to compounded drug products and effectively carrying out all aspects of the MOU will probably fall upon the taxpayer. States will have to find ways to fund these activities. One avenue might be to either institute or raise taxes on drugs and medicines, driving medical costs even higher. Other options for raising revenue would no doubt be explored and adopted. But in the end, it will inevitably be the consumer who will pay for these "services."

I understand from a letter written to me by Melinda K. Plaisier, Interim Associate Commissioner for Legislative Affairs for the FDA, that the draft MOU does not require a public review or comment period. In light of that, the FDA is to be commended for opening a public docket for comments and for also extending the comment period beyond its original deadline. My hope is that my concerns and those raised by others, including pharmacies and physicians involved in compounding drugs, will be thoughtfully considered by those responsible for this draft standard MOU and that a new Memorandum of Understanding will be drafted which will address these concerns and will more fairly implement the Modernization Act of 1997. If the problems lie with the Act itself, I would hope that the appropriate sections of the Act would be revisited and amended.

Sincerely,

Joan L. Brown

Joan L. Brown

cc: The Honorable Pete V. Domenici
United States Senate
Washington, D.C. 20510-3101

Melinda K. Plaisier
Interim Associate Commissioner for Legislative Affairs
Food and Drug Administration
Rockville, MD 20857

Joan L. Brown
325 Aragon Ave.
Los Alamos, NM 87544

HFW-14

Melinda K. Plaisier
Interim Associate Commissioner for Legislative Affairs
Food and Drug Administration
Rockville, MD 20857